



**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA 353]**

**Final Adjusted Assessment of Annual Needs for the List I Chemicals Ephedrine,  
Pseudoephedrine, and Phenylpropanolamine for 2012**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Notice.

**SUMMARY:** This notice establishes the Final Adjusted 2012 Assessment of Annual Needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**EFFECTIVE DATE:** [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]

**FOR FURTHER INFORMATION CONTACT:** John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

**SUPPLEMENTARY INFORMATION:** The 2012 Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and imported into the United States in 2012 to provide adequate supplies of each chemical for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks of such chemicals. Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires that the Attorney General establish an assessment of annual needs for ephedrine,

pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100.

On July 18, 2012, a notice entitled “Proposed Adjustment of the Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012” was published in the Federal Register (77 FR 42333). That notice proposed to adjust the 2012 Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion). All interested persons were invited to comment on or object to the proposed assessments on or before August 17, 2012.

### **Comments Received**

DEA did not receive any comments to the proposed adjustment of the assessment of annual needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale), and phenylpropanolamine (for conversion).

### **Conclusion**

In determining the adjusted 2012 assessments, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407 respectively). DEA considered changes in demand, changes in the national rate of net disposal, and changes in the rate of net disposal by the registrants holding individual manufacturing or import quotas for the chemical; whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; whether any increased demand could be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the assessment of annual

needs; whether any decreased demand would result in excessive inventory accumulation by all persons registered to handle the particular chemical; and other factors affecting the medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as found relevant.

Other factors that DEA considered include trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and export declarations. The inventory, acquisition (purchases), and disposition (sales) data as provided by DEA-registered manufacturers and importers reflects the most current information available to DEA at the time of publication of this Notice. The underlying data used to determine the final 2012 assessment of annual needs is the same as that used in determining the proposed 2012 assessment of annual needs, as published on September 14, 2011, at 76 FR 56809.

In accordance with 21 U.S.C. 826(a) and 21 CFR 1315.13, the Administrator hereby orders that the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, is adjusted and established as follows:

<b>List I Chemical</b>	<b>Final 2012 assessment of annual needs</b>
Ephedrine (for sale)	4,300 kg
Phenylpropanolamine (for sale)	5,800 kg
Pseudoephedrine (for sale)	278,000 kg
Phenylpropanolamine (for conversion)	26,200 kg
Ephedrine (for conversion)	12,000 kg

Dated: August 31, 2012

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Michele M. Leonhart  
Administrator

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